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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

PHARMACEUTICAL MANUFACTURING RESEARCH SERVICES, INC., Plaintiff-Petitioner, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, SCOTT GOTTLIEB, M.D., in his official capacity as the Commissioner of Food and Drugs, and his successors and assigns, and ERIC D. HARGAN, in his official capacity as the Acting Secretary of the United States Department of Health and Human Services, as well as his successors and assigns, Defendants.	**Civil Action No.**

Plaintiff-Petitioner Pharmaceutical Manufacturing Research Services, Inc. ("PMRS"), by and through its attorneys, McCarter & English, LLP, brings this action under the Administrative Procedure Act, 5 U.S.C. § 701, *et seq.*, for declaratory, injunctive, and other equitable relief against Defendants, the United States Food and Drug Administration ("FDA"), Scott Gottlieb, M.D., in his official capacity as the Commissioner of Food and Drugs, and his successors and assigns, and Eric D. Hargan, in his official capacity as the Acting Secretary of the United States Department of Health and Human Services, and his successors and assigns, to vacate FDA's

final decision of October 19, 2017, denying PMRS's Petition for Stay of Action. PMRS challenges FDA's final agency action in denying PMRS's PSA and says as follows for its Complaint against Defendants:

INTRODUCTION

1. This is an action for declaratory and injunctive relief arising from the Defendants' violation of: the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301, *et seq.*; FDA's regulations and policies implementing the FDCA; and the Administrative Procedure Act ("APA"), 5 U.S.C. § 706.

2. Specifically, this action seeks to vacate FDA's October 19, 2017, denial of PMRS's Petition for Stay of Action ("PSA" or "Petition"), a Petition that raises pressing public health issues.

3. That Petition was a timely request that FDA stay the effective date of its approval of Inspirion Delivery Services, LLC's New Drug Application 209777 for a product known as ROXYBOND (oxycodone hydrochloride) tablets, ("ROXYBOND" or "Inspirion NDA"), pending FDA's substantive responses to two pending Citizen Petitions previously submitted by PMRS before FDA's approval of ROXYBOND and pending FDA's substantive responses to certain stand-alone issues raised in PMRS's PSA pertaining specifically to the ROXYBOND approval..

4. PMRS's Citizen Petitions, as well as its public comments at numerous FDA meetings in recent years, highlighted several serious flaws in FDA's process for evaluating and approving opioids and sought to engage FDA in connection with the Agency's role in stemming the opioid epidemic plaguing this nation.

5. PMRS submitted the Petition for Stay to prevent another mislabeled and dangerous opioid from entering the market while FDA considers the life-and-death issues raised in PMRS's various submissions.

6. PMRS submitted the Petition for Stay in accordance with FDA's regulation mandating that such petitions must be submitted within 30 days of an agency's action . 21 C.F.R. § 10.35(b).

7. Those same regulations require a similarly prompt response from FDA. 21 C.F.R. § 10.35(e); Proposed Rule, 40 F.R. 40682 (Sept. 13, 1975)).

8. FDA took almost six months to respond to PMRS's PSA, providing a response only after PMRS filed a writ of mandamus to compel a response to its PSA and for other relief, which matter had been pending in the United States District Court, Eastern District of Pennsylvania, as *Pharmaceutical Manufacturing Research Services, Inc., v. United States Food and Drug Administration*, 2:17-cv-03507 (TJS).

9. As discussed below, FDA's response ignored many of the central issues raised by PMRS in its PSA and failed to address the critical health issues caused directly by FDA's approach to chronic use and abuse deterrent labeling in opioids.

10. As a result, and as discussed in more detail below, FDA's denial of PMRS's PSA was arbitrary, capricious, an abuse of discretion, and not in accordance with law, and in excess of statutory jurisdiction, authority, and limitations, within the meaning of 5 U.S.C. § 706(2)(A) and (C).

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction over this action pursuant to: (a) 28 U.S.C. § 1331 ("[t]he district courts shall have original jurisdiction of all civil actions arising

under the Constitution, laws, or treaties of the United States," *i.e.*, federal question jurisdiction); and § 1361("[t]he district courts shall have original jurisdiction of any action in the nature of mandamus to compel an officer or employee of the United States or an agency thereof to perform a duty owed to the plaintiff."); and (b) 5 U.S.C. §§ 555(b), 702, 706(1) (judicial review provisions of the APA).

12. The declaratory, injunctive, and other relief requested by PMRS is authorized by 5 U.S.C. § 702 and 706, by 28 U.S.C. §§ 1361, 1651, 2201, and 2202, and by this Court's general equitable powers.

13. Venue is proper in the Eastern District of Pennsylvania pursuant to 28 U.S.C. § 1391(e)(1)(C), because that is the District in which Plaintiff-Petitioner PMRS resides.

PARTIES

14. Plaintiff-Petitioner PMRS is a corporation with headquarters located at 202 Precision Road, Horsham, Pennsylvania 19044.

15. As a world-class supplier of pharmaceutical services, PMRS supports the manufacturing of four FDA-approved drug products, two internationally-approved drug products, and numerous developmental and investigational drugs.

16. PMRS is fully licensed by the United States Drug Enforcement Agency ("DEA") to handle controlled substances.

17. PMRS has held such licensing for more than 22 years, manufacturing controlled substances for a variety of pharmaceutical companies.

18. PMRS actively has been involved in research and development of opioids manufactured for abuse-deterrence for more than a decade.

19. PMRS has been issued two (2) patents from the United States Patent and Trademark Office for opioids formulated for abuse-deterrence and has another four (4) such patents pending.

20. Defendant FDA is an agency responsible for, among other duties, protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices.

21. FDA's headquarters are located at 10903 New Hampshire Avenue, Silver Spring, Maryland 20993.

22. FDA is headed by Defendant Scott Gottlieb, M.D., Commissioner of Food and Drugs, and operates under authority delegated by Congress and Defendant Eric D. Hargan, in his official capacity as the Acting Secretary of the United States Department of Health and Human Services ("HHS"), a federal agency headquartered in the District of Columbia.

23. Commissioner Gottlieb and Acting Secretary Hargan, and their respective successors and assigns, are sued in their official capacities as the government officials with ultimate responsibility for the actions and failures to act complained of herein.

FACTUAL BACKGROUND

A. The Opioid Epidemic and Its Impact on the Public Health

24. The United States of America is mired in a catastrophic opioid epidemic. *See* Robert M. Califf, M.D., et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. Engl. J. Med. 1480, 1483-85 (2016).

25. Statistics compiled by the Centers for Disease Control and Prevention ("CDC") demonstrate that, in 2014 alone, almost 2,000,000 Americans abused or were dependent on

prescription opioids and that opioids killed more than 33,000 people in 2015, more than any previous year on record.

26. CDC also reports that the number of opioid-related overdose deaths has quadrupled since 1999 and that 91 Americans die every day from an opioid overdose.

27. The public health crisis caused by the opioid epidemic has led to substantial economic harm as well. For example, in 2013 alone, the opioid epidemic resulted in approximately $78.5 billion in economic costs in the United States. C.S. Florence, et al., *The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States*, L. Med. Care. 2016 Oct. 54(10):901-06.

28. Analysis of opioid-related economic harms at the state level indicates that Pennsylvania ranks among the top 10 states in terms of total health care spending related to opioid abuse, with conservative estimates suggesting that the state spends $847 million per year on these costs—most likely significantly higher when the costs of opioid-abuse-related criminal justice and lost workplace productivity are taken into account. Matrix Global Advisors, *Health Care Costs from Opioid Abuse: A State-by-State Analysis*, at 2-4 (Apr. 2015), https://drugfree.org/wp-content/uploads/2015/04/Matrix_OpioidAbuse_040415.pdf (last visited Oct. 31, 2017).

29. In 2016, drug-related overdose deaths in Pennsylvania increased by 37 percent from 2015, and the Pennsylvania drug-related overdose death rate remained significantly higher than the national average. DEA, *Analysis of Overdose Deaths in Pennsylvania, 2016* (Jul. 2017), at 5, https://www.overdosefreepa.pitt.edu/wp-content/uploads/2017/07/DEA-Analysis-of-Overdose-Deaths-in-Pennsylvania-2016.pd_-1.pdf (last visited Oct. 31, 2017).

30. Philadelphia led the nation in 2015 in drug overdose deaths among young adult men. Don Sapatkin, *Pa. leads nation in young men's overdose deaths, N.J. 4th*, The Philadelphia Inquirer (updated Nov. 20, 2015, 1:08 AM EST), http://www.philly.com/philly/health/addiction/20151120_Pa___N_J__lead_nation_in_young_men_s_overdose_deaths.html (last visited Oct. 31, 2017).

31. On October 26, 2017, in response to the escalating crisis, President Donald J. Trump directed the Department of Health and Human Services to declare the opioid crisis a public health emergency.

32. President Trump noted that, "[n]o part of our society – not young or old, rich or poor, urban or rural – has been spared this plague of drug addiction and this horrible, horrible situation that's taken place with opioids."

33. Accordingly, President Trump declared the opioid epidemic "a national health emergency."

34. FDA's entrenched regulatory approach is unlawful and has significantly contributed to this national health emergency.

35. Notwithstanding insufficient data to support chronic use, FDA persists in labeling opioids as appropriate for chronic use.

36. FDA's efforts to address the crisis have only compounded the problem, with FDA permitting a wave of opioids labeled as abuse-deterrent to flood the market, despite the absence of sufficient data to support those claims.

37. That regulatory approach has resulted in confusion with respect to the safety and efficacy of opioids labeled for chronic use and abuse deterrence.

38. In the face of FDA's persistence with its current regulatory approach, the number of Americans becoming addicted to opioids and dying each year has skyrocketed.

B. Insufficient Data to Support Use of Opioids for Chronic Pain

39. FDA defines chronic pain as "either pain persisting for longer than 1 month beyond resolution of the underlying insult, or pain persisting beyond 3 months." *See, e.g.*, FDA, *Guidance for Industry—Analgesic Indications: Developing Drug and Biological Products*, at 2 (Feb. 2014), https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM384691.pdf (last visited Oct. 31, 2017).

40. Critically, however, after conducting a comprehensive review of the scientific evidence supporting the effectiveness of long-term opioid therapy for chronic pain, the CDC found that:

> Most placebo-controlled, randomized trials of opioids have lasted 6 weeks or less, and we are aware of no study that has compared opioid therapy with other treatments in terms of long-term (more than 1 year) outcomes related to pain, function, or quality of life. The few randomized trials to evaluate opioid efficacy for longer than 6 weeks had consistently poor results.

Thomas R. Frieden & Debra Houry, *Reducing the Risks of Relief — The CDC Opioid-Prescribing Guideline*, 374 New Eng. J. Med. 1501, 1501 (2016).

41. Indeed, in its March 2016 *Guideline for Prescribing Opioids for Chronic Pain*, the CDC found that "[t]he evidence reviews forming the basis of this guideline clearly illustrate that there is much yet to be learned about the effectiveness, safety, and economic efficiency of long-term opioid therapy." CDC, *Guideline for Prescribing Opioids for Chronic Pain*, at 34 (2016), https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf (last visited Oct. 31, 2017).

42. Thus, the CDC concluded that, "[t]he science of opioids for chronic pain is clear: for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits." Frieden & Houry, *Reducing the Risks of Relief — The CDC Opioid-Prescribing Guideline*, 374 New Eng. J. Med. at 1503.

43. For approval, a drug must be determined to be safe for use and effective. 28 U.S.C. § 505(b).

44. An applicant must provide substantial evidence of efficacy for the conditions of use approved.

45. To provide substantial evidence, an applicant must conduct adequate and well-controlled studies. 21 U.S.C. 355(b).

46. For analgesic products, FDA anticipates at least two adequate and well-controlled studies.

47. FDA has stated that the Agency "is not aware of adequate and well-controlled studies of opioid use longer than 12 weeks." FDA Response to Physicians for Responsible Opioid Prescribing (PROP) Citizen Petition (Sep. 10, 2013), at 10 , https://www.regulations.gov/document?D=FDA-2012-P-0818-0793 (last visited Oct. 31, 2017).

48. FDA has also stated that, while the evidence base is strong for the efficacy of opioids for up to 12 weeks of treatment, their performance and liabilities beyond 12 weeks have not been demonstrated "in the type of evidentiary base that FDA usually has for approval for when [the Agency] grant[s] an indication." FDA, Transcript, *Assessment of Analgesic Treatment of Chronic Pain: A Scientific Workshop* (May 31, 2012), at 7-8 (statement of Janet Woodcock, M.D., Director, CDER), https://www.regulations.gov/document?D=FDA-2012-N-0067-0017 (last visited Oct. 31, 2017).

49. In its comprehensive *Guideline for Prescribing Opioids for Chronic Pain*, CDC reported that "[t]he clinical evidence review found insufficient evidence to determine long-term benefits of opioid therapy for chronic pain and found an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent." CDC, *Guideline for Prescribing Opioids for Chronic Pain*, at 13 (2016), https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf (last visited Oct. 31, 2017).

50. Indeed, in response to the CDC's report, FDA has acknowledged that "[a] key lesson learned during the development of the CDC guideline is that there is very little research on the long-term benefits of opioids for treating chronic pain[,]" in contrast to the "growing evidence of harms associated with such use, and of the benefits of other nonopioid treatment alternatives." Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*, 374 New Eng. J. Med. at 1484.

51. Further, FDA has acknowledged that the Agency "does its best work when high-quality scientific evidence is available to assess the risks and benefits of intended uses of medical products" but that "[u]nfortunately, the field of chronic pain treatment is strikingly deficient in such evidence." *Id.* at 1484.

52. In stark contradiction to both the CDC's findings and its own public statements, FDA continues to approve new opioid products intended for the treatment of chronic pain.

C. PMRS's Identification of Systemic Flaws in FDA's Process for Reviewing and Approving Opioids

53. PMRS's own research and development has revealed systemic flaws with FDA's review and approval of opioids that are undermining FDA's ability to protect the public health and welfare in the face of the opioid-addiction epidemic.

54. Pursuant to 21 C.F.R. §§ 10.20 and 10.30, PMRS raised those critical issues with FDA via Citizen Petitions dated February 19, 2016, and March 6, 2017.[1]

55. In its interim responses, FDA conceded that PMRS has raised complex issues of public policy and welfare.

56. Yet in its denial of PMRS's PSA, FDA makes a sweeping and conclusory declaration that neither Citizen Petition warrants staying the effective approval date of ROXYBOND.

57. In other words, FDA's position is to stay the course, figuring it out and fixing it later.

(1) ***PMRS's February 2016 Citizen Petition***

58. On February 19, 2016, PMRS submitted a citizen petition to FDA directed at the issue of abuse-deterrent labeling ("February 2016 Citizen Petition"), pending under Docket No. FDA-2016-P-0645, requesting, in part, that FDA take certain actions, summarized as follows:

a. Apply the existing standards for laboratory-based in vitro manipulation and extraction studies, including both small and large volume extraction, before permitting opioid drug products with potentially abuse-deterrent properties to be approved;

b. Remove Category 3 human abuse-deterrent (liking) studies from the FDA Guidance, "Abuse-Deterrent Opioids Evaluation and Labeling Guidance for Industry" (April 2015), and as a requirement for approval of drug products with potentially abuse deterrent properties as inherently flawed, subjective, and highly prone to manipulation; and

c. Require post-marketing empirical proof through epidemiological or other scientifically rigorous studies that shows that opioid drug products with potential abuse deterrent properties do in fact result in a *meaningful* reduction in misuse, abuse, addiction, overdose and/or death before approving abuse deterrent labeling for opioid drug products and before permitting opioid drug products to be marketed as abuse deterrent.

[1] PMRS's Citizen Petitions are pending under docket numbers FDA-2016-P-0645 and FDA-2017-P-1359.

59. PMRS's February 2016 Citizen Petition also requested that all opioid drug products currently labeled with abuse-deterrent claims be required to meet all three of the requirements specified above or have their abuse-deterrent labeling removed within a reasonable period of time not to exceed six months.[2]

(2) *PMRS's March 2017 Citizen Petition*

60. On March 6, 2017, PMRS submitted a citizen petition to FDA directed at the issue of chronic-use labeling, now pending under Docket No. FDA-2017-P-1359 ("March 2017 Citizen Petition"), requesting, in part, the revocation of all immediate-release ("IR") opioid drug product labeling that "support[s] use for the treatment of chronic pain." PMRS further requested that all IR opioid drug product labeling state that the indication is for "acute pain for a limited duration."

(3) *FDA's Failure to Respond Substantively to PMRS's Citizen Petitions*

61. PMRS has raised the above-discussed issues directly with FDA on multiple occasions, publicly advocating for the agency to reassess its approach to approving opioid products.

62. In addition to its two Citizen Petitions, PMRS also has participated in numerous FDA Advisory Committee meetings and public workshops. *See generally* PMRS's comments at the advisory committee meetings pertaining to VANTRELA ER (Jun. 7, 2016), TROXYCA ER (Jun. 8, 2016), ARYMO ER (Aug. 4, 2016), the use of opioids in pediatric patients (Sep. 16, 2016), OPANA ER (Mar. 14, 2017), ROXYBOND (Apr. 5, 2017), and REXISTA (Jul. 26,

[2] In addition, the February 2016 Petition included a request for actions pertaining to OXYCONTIN specifically. (February 2016 Petition, No. FDA-2016-P-0645 at 4.) The OXYCONTIN-specific requests are not addressed in this action.

2017), as well as the public meeting on premarket evaluation of abuse-deterrent properties (Nov. 1, 2016).

63. To date, however, PMRS has received no substantive response to its Citizen Petitions, no substantive information, and no substantive rationale for FDA's continuation of a seemingly status quo approach that permits flooding the market with opioids labeled as abuse-deterrent and appropriate for chronic use, despite the absence of sufficient data to support those claims.

D. PMRS's May 11, 2017 Petition for Stay of Action

64. Notwithstanding the significant public-health issues discussed in PMRS's various submissions, and notwithstanding FDA's acknowledgment of CDC findings confirming the lack of sufficient data to support use of opioids to treat chronic pain, on April 20, 2017, FDA approved the Inspirion NDA.

65. FDA's treatment of the Inspirion NDA creates a rigid and harmful dichotomy, wherein FDA delays responding substantively to PMRS's Citizen Petitions that raise fundamental questions about FDA's role in facilitating the opioid epidemic, but then rushes to approve yet another opioid product with chronic use labeling and purported abuse-deterrent properties, despite the scientific community's recognition that the evidence needed to support such claims is lacking.

66. On May 11, 2017, and within the 30-day window mandated by FDA, PMRS filed a Petition for Stay of Action ("PSA") pursuant to 21 C.F.R. § 10.35, requesting that FDA stay the effective approval date of ROXYBOND until such time as FDA provides substantive responses to: (1) PMRS's Citizen Petitions, which raised serious safety issues concerning opioids such as ROXYBOND, which are approved for chronic use and/or as abuse-deterrent; and (2) the

substantive issues raised in PMRS's PSA, which also raised serious safety issues concerning ROXYBOND.

67. After 30 days passed with no response from FDA, PMRS sent Commissioner Gottlieb a letter to ensure his awareness of the PSA and to reiterate the urgency of PMRS's PSA.

68. After waiting months for a response, PMRS filed, *inter alia*, a petition for writ of mandamus seeking to compel FDA to respond to PMRS's petition to stay the effective approval date of ROXYBOND promptly.

E. FDA's Denial of PMRS's PSA on October 19, 2017.

69. On October 20, 2017, shortly before the Rule 16 Conference scheduled on PMRS's petition for writ of mandamus and other relief, counsel for FDA electronically transmitted a purported denial letter to PMRS's counsel, contending that the denial letter had been sent to PMRS on October 19, 2017 ("FDA's denial letter").

70. As of the date of the filing of the Complaint, the purported denial letter has not been posted to FDA's docket as required pursuant to 21 C.F.R. 10.35.

71. In its denial letter, FDA recognized the critical threat posed by this country's opioid epidemic.

72. In its denial letter, FDA also acknowledged that PMRS raised "critical public health subject[s]" in its Citizen Petitions and PSA that are complex and, per FDA, warrant detailed inquiry.

73. Yet FDA denied PMRS's petition to stay the effective approval date of ROXYBOND without offering any basis for continuing to approve opioids such as ROXYBOND during the pendency of FDA's review of the very issues that FDA itself has

recognized are of critical importance to the public health, including a review of FDA's method of approving opioids.

74. Instead, FDA offers only a conclusory and unsupported assertion that PMRS failed to establish sound public policy grounds supporting a stay, despite recognizing the fundamental public policy and health issues raised in PMRS's Citizen Petitions and PSA.

75. Specifically, in its denial letter, FDA offered no explanation for its repeated approval of opioid drug products for the treatment of chronic pain, despite lacking substantial evidence to support the efficacy of these products in the chronic use setting.

76. FDA also offered no explanation for its failure to adhere to its own existing recommendations for laboratory-based *in vitro* manipulation and extraction studies when evaluating opioid drug products with potentially abuse-deterrent properties.

77. FDA offered no response to PMRS's arguments concerning FDA's troubling reliance on HAP studies, which are inherently flawed.

78. FDA offered no response to PMRS's position regarding the dangers inherent in failing to require postmarketing proof of abuse-deterrent labeling before permitting labeling for abuse-deterrence.

79. FDA did not explain how the approval of ROXYBOND with labeling claims pertaining to chronic use and abuse deterrence was in compliance with the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.*, ("FDCA") and with the Agency's own regulations and guidance.

80. For example, FDA did not explain the bases for its conclusion that the approval of ROXYBOND was supported by substantial evidence of efficacy and safety.

81. FDA also did not explain how the approval of ROXYBOND was consistent with the Agency's ADF guidance, even though PMRS's PSA specifically highlighted several issues with the approval, such as the flawed particle size manipulation study and the failure of ROXYBOND's sponsor to use the product manipulation that caused the highest release of the opioid and the highest plasma levels in the HAP study.

82. In other words, FDA failed to respond to relevant arguments made by PMRS and failed to provide necessary findings and reasoning.

83. In light of the facts set forth herein and above, FDA's denial was arbitrary, capricious, an abuse of discretion, not in accordance with law, and in excess of statutory jurisdiction, authority, and limitations, within the meaning of 5 U.S.C. § 706(2)(A) and (C).

CLAIM FOR RELIEF
COUNT I
(Administrative Procedure Act)

84. The foregoing allegations are incorporated by reference and repeated as though set forth in full herein.

85. FDA is an agency subject to the requirements of the APA. 5 U.S.C. §§ 701 and 706.

86. "[A]gency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law" shall be held "unlawful and set aside." *Id.* §706(2)(A).

87. An agency action also must be deemed unlawful and set aside if it is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right…." *Id.* §706(2)(C).

88. FDA's October 19, 2017, denial of PMRS's PSA is a final agency action within the meaning of 5 U.S.C. §704.

89. FDA's denial was arbitrary, capricious, an abuse of discretion, and not in accordance with law, and in excess of statutory jurisdiction, authority, and limitations, within the meaning of 5 U.S.C. § 706(2)(A) and (C).

90. PMRS has no other adequate remedy in a court.

91. FDA's action should be vacated pursuant to 5 U.S.C. § 706(2).

COUNT II
(Declaratory Relief)

92. The foregoing allegations are incorporated by reference and repeated as though set forth in full herein.

93. An actual controversy within the meaning of Article III of the United States Constitution exists between PMRS and Defendants as to whether the denial of PMRS's PSA violates the Agency's regulations and is arbitrary, capricious, an abuse of discretion, and not in accordance with law, and in excess of statutory jurisdiction, authority, and limitations.

94. PMRS is entitled to a declaration that the actions of the Defendants as set forth herein are arbitrary, capricious, an abuse of discretion, and not in accordance with law, and in excess of statutory jurisdiction, authority, and limitations, within the meaning of 5 U.S.C. § 706(2)(A) and (C).

COUNT III
(Injunctive Relief)

95. The foregoing allegations are incorporated by reference and repeated as though set forth in full herein.

96. Defendants' acts are arbitrary, capricious, an abuse of discretion, and not in accordance with law, and in excess of statutory jurisdiction, authority, and limitations, within the meaning of 5 U.S.C. § 706(2)(A) and (C).

97. The public already has suffered serious injury, including skyrocketing addiction, overdose, and death rates.

98. The public will face irreparable harm as a direct and proximate result of the Defendants' failure to approve PMRS's PSA should ROXYBOND launch before FDA raises the issues set forth in PMRS's pending citizen petitions and PSA, particularly as practitioners and patients develop a false sense of security around ROXYBOND, another opioid promoted for chronic use and labeled as abuse deterrent.

99. PMRS is entitled to a temporary injunction staying the effective approval date of ROXYBOND during the pendency of FDA's review of the substantive issues raised in PMRS's pending citizen petitions and PSA.

100. Other remedies are unavailable or futile.

101. PMRS has experienced harm and will experience irreparable harm if ROXYBOND is permitted to launch before FDA decides PMRS's Citizen Petitions and the substantive issues raised in PMRS's PSA.

102. PMRS will face an increased risk of being subject to procedural disadvantages associated with the approval process for its own proposed product.

103. FDA granted ROXYBOND priority review.

104. FDA declined to grant PMRS priority review.

105. Additionally, PMRS will be harmed if ROXYBOND is first to market.

106. The critical importance of being first to market is well-established in the pharmaceutical industry.

107. Companies spend considerable research seeking to increase the odds of beating their competitors to market because of the significant commercial disadvantage to missing first approval.

108. In the industry, every month of lead time ahead of a competitor is significant.

109. First-approved and first-moved products are able to establish themselves with physicians and patients in a way that cannot be changed after the fact.

110. FDA's failure to act grant PMRS's PSA, therefore, is causing substantial and irreparable harm to PMRS.

WHEREFORE, Plaintiff-Petitioner PMRS prays that this Court enter an Order:

a. Setting aside FDA's denial of PMRS's petition for stay of action as arbitrary, capricious, an abuse of discretion, and not in accordance with law, and in excess of statutory jurisdiction, authority, and limitations, within the meaning of 5 U.S.C. § 706(2)(A) and (C);

b. Preliminarily staying the effective date of Inspirion Delivery Services, LLC's New Drug Application 209777 for ROXYBOND (oxycodone hydrochloride) tablets until Defendants issue a substantive response to the substantive issues raised in PMRS's PSA and pending citizen petitions; and

c. Awarding PMRS attorneys' fees, reasonable expenses incurred in connection with this action, and such other relief as this Court deems equitable, just, and proper

under the circumstances.

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Dated: October 31, 2017

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